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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,571	02/24/1998	CHARLES R. CANTOR	25491-2401G	7542

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/05/2002

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/030,571

Applicant(s)

CANTOR ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-79, 89-94 and 114-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-79, 89-94 and 114-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Restrictions

1. Applicant's election without traverse of Group III, Claims 70-79, 89-94 and 114-116 in Paper No. 29 is acknowledged.

Applicant's cancellation of Claims 1-5, 65-69, 80-88, 95-113 and 117-122 in Paper No. 29 is acknowledged.

Claims 70-79, 89-94 and 114-116 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 115 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 115 is indefinite for the recitation "wherein the number of probes contained within the array is such that the number of random sequences within the array permits determination of the nucleotide sequence of a target nucleic acid by hybridization of the target to the array" because it is unclear what structural limitations are being described. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 70-74, 76-79, 89, 91-94 and 114-116 are rejected under 35 U.S.C. 102(e) as being anticipated by Deugau et al (U.S. Patent No. 5,508,169, filed 6 April 1990).

Regarding Claim 70, Deugau et al disclose an array of nucleic acid probes wherein each probe has a double-stranded portion and a single stranded portion and a random nucleotide sequence of length R within the single-stranded portion (Column 9, lines 29-42 and Claim 33).

Regarding Claim 71, Deugau et al disclose the array comprising about 4ⁿ different nucleic acid probes i.e. comprehensive panel (Column 8, lines 25-30 and Claims 33).

Regarding Claim 72, Deugau et al disclose the array wherein the double-stranded portion (i.e. common sequence # 1026, # 1504 and # 1701) is between about 3-20 nucleotide

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and the single stranded portion is between about 3-20 nucleotides (Columns 15-16, Table I and Table II).

Regarding Claim 73, Deugau et al disclose the array wherein the double-stranded portion (i.e. common sequence # 1026, # 1504 and # 1701) is between 3-20 nucleotide and the single stranded portion is between 3-20 nucleotides (Columns 15-16, Table I and Table II)

Regarding Claim 74, Deugau et al disclose the array wherein the probes are fixed to a solid support (Column 10, lines 45-51 and Claim 26).

Regarding Claim 76, Deugau et al disclose the array wherein the solid support is a two-dimensional matrix with multiple probe binding sites i.e. the probes are attached to spatially segregated solid phase substrates (Column 10, lines 45-51).

Regarding Claim 77, Deugau et al disclose the array wherein the probes are labeled with a detectable label (Claim 27).

Regarding Claim 78, Deugau et al disclose the array wherein the label comprises a radioisotope or fluorescent chemical (Claims 27 & 28).

Regarding Claim 79, Deugau et al disclose the array wherein the nucleic acids are DNA (Claims 25 and 33).

Regarding Claim 89, Deugau et al disclose a solid support comprising an array of nucleic acid probes wherein each probe has a double-stranded portion, a single stranded portion and a random sequence of length R within the single-stranded portion (Column 9, lines 29-42 and Claims 26 and 33).

Regarding Claim 91, Deugau et al disclose the solid support wherein the solid support is a two-dimensional matrix with multiple probe binding sites i.e. the probes are attached to spatially segregated solid phase substrates (Column 10, lines 45-51).

Regarding Claim 92, Deugau et al disclose the solid support wherein the probes are labeled with a detectable label (Claim 27).

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Regarding Claim 93, Deugau et al disclose the solid support wherein the label comprises a radioisotope or fluorescent chemical (Claims 27 & 28).

Regarding Claim 94, Deugau et al disclose the solid support wherein the nucleic acids are DNA (Claims 25 and 33).

Regarding Claim 114, Deugau et al disclose an array of nucleic acid probes wherein each probe has a double-stranded portion comprising a constant sequence, a single-stranded portion and a random nucleotide sequence within the single-stranded portion (Column 9, lines 28-42).

Regarding Claim 115, Deugau et al disclose the array of Claim 70 containing less than 4^r probe wherein the number of probes contained within the array is such that the number of random sequences within the array permits determination of the nucleotide sequence of a target nucleic acid by hybridization of the target to the array (Claim 25). The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Because Deugau et al disclose the structural limitations of the claim, and because the courts have stated that recitation of an intended use does not differentiate an apparatus from the prior art, the functional language recited in the claim (i.e. "wherein the number of probes contained within the array is such that the number of random sequences within the array permits determination of the nucleotide sequence of a target nucleic acid by hybridization of the target to the array") does not differentiate the claimed array from the array of Deugau et al.

Regarding Claim 116, Deugau et al disclose a solid support comprising an array of nucleic acid probes wherein each probe has a double-stranded portion comprising a constant sequence, a single-stranded portion and a random nucleotide sequence within the single-stranded portion (Column 9, lines 28-42 and Claims 26 and 33).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 75 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deugau et al (U.S. Patent No. 5,508,169, filed 6 April 1990) in view of Ghosh et al (Nucleic Acids Research, 1987, 15: 5353-5372).

Regarding Claim 75, Deugau et al teach an array of nucleic acid probes wherein each probe has a double-stranded portion and a single stranded portion and a random nucleotide sequence of length R within the single-stranded portion (Column 9, lines 29-42 and Claim 33) wherein the probes are fixed to a solid support as taught by Ghosh et al (Column 10, lines 45-51 and Claim 26) but they do not specifically teach the material from which the solid support is made. However, Ghosh et al teach their solid support is selected from plastics and resins (page 5356, first full paragraph-page 5357, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the solid supports of Ghosh et al to the immobilization of Deugau et al and to immobilize the probes onto plastic or resin support based on the suggestion of Deugau et al (Column 10, lines 45-51 and Claim 26) thereby utilizing well known supports for the expected benefits of successful immobilization.

Regarding Claim 90, Deugau et al teach a solid support comprising an array of nucleic acid probes wherein each probe has a double-stranded portion, a single stranded portion and a random sequence of length R within the single-stranded portion (Column 9, lines 29-42 and

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Claims 26 and 33) wherein the probes are fixed to a solid support as taught by Ghosh et al (Column 10, lines 45-51 and Claim 26) but they do not specifically teach the material from which the solid support is made. However, Ghosh et al teach their solid support is selected from plastics and resins (page 5356, first full paragraph-page 5357, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the solid supports of Ghosh et al to the support of Deugau et al and to immobilize the probes onto plastic or resin support based on the suggestion of Deugau et al (Column 10, lines 45-51 and Claim 26) thereby utilizing well known supports for the expected benefits of successful immobilization.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 70-73, 114 and 115 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 7 of U.S. Patent No. 6,007,987. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because both sets of claims are drawn to an array of nucleic acid probes and differ only in the patent claim being drawn to a product by process while the instant claims are drawn to a product. However, the courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Therefore, even though the patent array may be made by a defined process, that process does not patentably distinguish the instant array from the patent array. Hence, the instantly claimed arrays are obvious over the patent arrays.

10. Claims 74-76, 89-94 and 116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 7 of U.S. Patent No. 6,007,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array of nucleic acid probes while the instant claims are drawn to a solid support comprising the array. However the phrase “an array of nucleic acid probes” broadly interpreted encompasses the instantly claimed solid support comprising an array because one of skill in the art at the time the claimed invention was made would reasonably interpret the term “array” to encompass a solid support. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). Alternatively, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify

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the patent array and to immobilize the array as instantly claimed to thereby provide for immobilized and localized hybridization for the expected benefits of simplified identification of hybridization reactions.

11. Claims 70-70, 89-94 and 114-116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-6 of U.S. Patent No. 6,007,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are drawn to a method of making an array of probes and the instant claims are drawn to an array of probes made by the patent method. The instantly claimed array of probes is obvious over the method of making the array because the patent method obviously makes the instantly claimed array.

12. Claims 70-79, 89-94 and 114-116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,631,134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are drawn to a method of making an array of probes and the instant claims are drawn to an array of probes made by the patent method. The instantly claimed array of probes is obvious over the method of making the array because the patent method obviously makes the instantly claimed array.

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NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

13. This application contains sequence disclosures (e.g. pages 23-24 and page 48) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given A PERIOD OF TIME WHICH IS CO-EXTENSIVE WITH THE TIME TO REPLY TO THE ABOVE OFFICE ACTION within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 21, 2002